United States Court of Appeals

for the Second Circuit

APPELLEE'S BRIEF

w/ affidavit

74-2477

To be argued by
JERRY L. SIEGEL

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 74-2477

B

STERLING DRUG, INC., WINTHROP PRODUCTS, INC. and BREON LABORATORIES, INC.,

Plaintiffs-Appellants.

—against—

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

P/S

BRIEF OF DEFENDANTS-APPELLEES

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STATEMENT OF THE CASE

This is an appeal from an order of the Honorable Lawrence W. Pierce, United States District Judge, dated and filed October 31, 1974, denying plaintiff's motion for a preliminary injunction and dismissing the complaint.

The Food and Drug Administration ("FDA") published in the Federal Register of August 13, 1974 a notice of its intent to withdraw approval of the drug Alevaire, apprising plaintiffs of the opportunity for a hearing on that proposed action. The notice indicated that, based upon a study of

Alevaire conducted by the National Academy of Sciences - National Research Council and other information before it, the agency had determined that Alevaire was an ineffective product, and that lacking substantial evidence of effectiveness, approval thereof should be withdrawn. Plaintiffs instituted this action on September 30, 1974, seeking by their complaint both to preliminarily and then to permanently enjoin the FDA from proceeding on the grounds (1) that the proposed action was barred by the doctrines of res judicata and collateral estoppel as a result of prior proceedings in the Court of Appeals, and (2) that the agency lacked any "new information" as a basis for its proposed action, as required by the statute.

On October 10, 1974, a hearing* was held before Judge Pierce at which time the motion for a preliminary injunction was consolidated with the trial on the merits pursuant to Rule 65(a)(2), Federal Rules of Civil Procedure.

By stipulation of the parties and at the Court's suggestion, the time to file materials with the agency in support of the request for a hearing was extended from

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* The hearing was to consist of oral argument by counsel only until the District Judge, at the commencement of the proceedings, suggested Rule 65(a)(2) consolidation. No testimony was taken. At the close of the proceedings, the government, for purposes of its motion to dismiss, conceded that if opposing counsel themselves testified as to the prior proceedings, their testimony would be as they alleged, without conceding the truth thereof (A 196).

October 15, 1974 to a date fifteen days after the entry of the Court's decision (A 155).

In the Memorandum Opinion dated and filed on October 31, 1974, the District Judge denied the motion for a preliminary injunction and dismissed the complaint for failure to exhaust administrative remedies, since the plaintiffs had not yet submitted any evidence in support of their request for a hearing and the agency had not yet taken any final action with respect to their product (A 204).

Following the entry of a final order on November 6, 1974, plaintiffs filed a notice of appeal and moved for an injunction pending appeal. On November 12, 1974, this Court directed that the appeal be expedited and heard the week of December 16, 1974. Once again, the plaintiffs' time within which to file materials with the agency was extended until oral argument. As of this date, December 10, 1974, they have not filed any materials with the agency.

THE ISSUES ON APPEAL

1. Did the District Court err in refusing to enjoin the Food and Drug Administration proceedings and in requiring appellants to exhaust their administrative remedies by presenting their claims of res judicata/collateral estoppel and lack of "new information" to the agency itself in the first instance, and permitting the agency to pass upon them, before seeking judicial review of those claims?

2. Assuming arguendo that appellants need not exhaust their administrative remedies, does the prior opinion of this Court finding improper notice to have been given or the agency's own action in attempting to withdraw approval of what it has determined to be an ineffective drug, in any way bar the agency from thus proceeding?

3. Assuming arguendo that appellants need not exhaust their administrative remedies, do the 1968 study of the drug Alevaire by the National Academy of Sciences - National Research Council finding it to be ineffective and the agency's own study of the labelling of the product colorably constitute "new information" that the product lacks substantial evidence of effectiveness, as required by 21 U.S.C. § 355(e)?

STATEMENT OF FACTS

A. The Statutory Procedures for Withdrawing Approval of A New Drug Application

As originally enacted in 1938, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. provided that the Food and Drug Administration could deny approval, or withdraw approval previously granted a drug, only if it found the drug to be unsafe for its intended use. In 1962, Congress amended the Act to require further that all drugs on the market be proven effective for their intended use.

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21 U.S.C. § 355(e).*

Faced with the task of reviewing the efficacy of all drugs permitted on the market between 1938 and 1962 which had theretofore been evaluated for safety only, the FDA retained the National Academy of Sciences - National Research Council ("NAS-NRC") in 1966 to conduct surveys of all such drugs. After asking drug manufacturers to submit information and evidence concerning the effectiveness of their drugs, the NAS-NRC completed and began submitting its first reports in October, 1967 and continued to do so over the next eighteen months. In January of 1968, the FDA began implementation of these studies by evaluating each report and on the basis thereof, rating each drug tested as being "effective," "probably effective", "possibly effective", or "lacking substantial evidence of effectiveness." Follow-

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* 21 U.S.C. § 355(e) provides in pertinent part:

> The Secretary shall, after due notice and opportunity for a hearing to the applicant, withdraw approval of an application with respect to any drug under this secton if the Secretary finds . . . (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof . . .

ing publication of its determination in the Federal Register, the FDA affords the drug manufacturers a period of time within which to provide evidence of effectiveness in any case in which the drug has been determined by the FDA to be anything other than "effective".

During this period, the manufacturer is permitted to continue marketing the drug. If, at the end of the interim period, however, no studies have been undertaken or if such studies do not provide "substantial evidence"* of effectiveness, approval of the drug is withdrawn pursuant to the procedure set forth in Section 355(e).

Under Section 355(e) and the applicable regulations, the Secretary is required to notify the manufacturer of his intent to withdraw approval, and of "the grounds upon which he proposes to issue his order" by publication in the Federal Register. Such notice must also notify the manufacturer of

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* "Substantial evidence", as used in Section 355(e) is defined by section 355(d) to mean:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

an opportunity for a hearing on the proposed action. 21 C.F.R. § 314.200(a). The manufacturer then has 30 days within which to file a notice of appearance and request for a hearing, and 60 days from the date of the notice within which to submit "the studies on which he relies to justify a hearing". 21 C.F.R. § 314.200(c)(1). A "request for a hearing shall be supported only by adequate and well-controlled clinical studies meeting all the precise requirements of § 314.111(a)(5) and, for combination drug products, § 3.86 ... No other data, information, or studies shall be submitted." § 314.200(d)(1) (emphasis supplied).*

If it conclusively appears from the data submitted that

> "there is no genuine and substantial issue of fact which precludes ... the withdrawal of approval ... e.g. no adequate and well-controlled clinical investigations meeting each of the precise elements [of the enumerated regulations], the Commissioner will enter summary judgment against the person(s) who requests the hearings making findings and conclusions, denying a hearing, ... and shall specify why each study submitted fails to

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* While the precise criticisms of a particular drug made by the NAS-NRC study and the FDA were made known only upon the publication of these notices in the Federal Register, the manufacturers and distributors knew in 1962 that under the Act as amended, they would be called upon to produce evidence of their products' effectiveness at some time in the future. See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619-621 (1973) quoted infra at 9.

> meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact ..." 21 C.F.R. § 314.200(g)(1).

This summary judgment procedure has been scrutinized by the Courts and repeatedly sustained. As Judge Friendly wrote in Pfizer, Inc. v. Richardson, 434 F.2d 536, 543 (CA 2 1970):

> "While the controversy over a particular drug raises an issue of 'ajudicative facts' [cite omitted] we perceive no denial of due process in Congress directing an agency that it need not accord a trial-type hearing unless the affected party shows in advance that there is something substantial to hear."

See also USV Pharmaceutical Corp. v. HEW, 466 F.2d 455 (CA DC 1972); CIBA-GEIGY Corp. v. Richardson, 446 F.2d 466 (CA 2 1971); Upjohn Co. v. Finch, 422 F.2d 944 (CA 6 1970).

More recently, the Supreme Court itself in Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609 (1973) explored the reasons for the use of this procedure and explicitly approved it. As the Court observed:

> We cannot impute to Congress the design of requiring, nor does due process demand, a hearing when it appears conclusively from the applicant's "pleadings" that the application cannot succeed. [footnote omitted].
>
> The NAS-NRC panels evaluated approximately 16,500 claims made on behalf of the 4,000 drugs marketed pursuant to effective NDA's in 1962. Seventy percent of these claims were found

not to be supported by substantial evidence of effectiveness, and only 434 drugs were found effective for all their claimed uses. If FDA were required automatically to hold a hearing for each product whose efficacy was questioned by the NAS-NRC study, even though many hearings would be an exercise in futility, we have no doubt that it could not fulfill its statutory mandate to remove from the market all those drugs which do not meet the effectiveness requirements of the Act.

If this were a case involving trial by jury as provided in the Seventh Amendment, there would be sharper limitations on the use of summary judgment, as our decisions reveal. [citations omitted] But Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labelled in mysterious scientific dress. The standard of "well-controlled investigations" particularized by the Regulations is a protective measure designed to ferret out those drugs for which there is no affirmative reliable evidence of effectiveness. The drug manufacturers have full and precise notice of the evidence they must present to sustain their NDA's and under these circumstances we find FDA hearing regulations unexceptionable on any statutory or constitutional ground. (emphasis supplied). 412 U.S., at 619-21*

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* Throughout their brief, appellants intimate that the agency's actions in this case were somehow motivated by the "adverse" decision of the Supreme Court in this case. A reading of this decision and those in the related cases indicates that the agency's position was sustained in each.

(Footnote continued on next page)

If the agency finds that there are genuine and substantial issues of fact which justify a hearing or that it would otherwise be in the public interest to hold a hearing, the Commissioner issues a notice defining the issues and naming an administrative law judge to preside at a hearing to be held within 90 days. 21 C.F.R. § 314.200 (g)(6). The hearing is then conducted pursuant to the procedures outlined in 21 C.F.R. § 314.200(h)-314.232, which provide for the presentation and cross-examination of witnesses, oral and written argument by counsel, the taking of evidence, and the issuance of written findings of fact and of a final order.

B. The Proceedings Against Alevaire

Since the history of the proceedings involving Alevaire is satisfactorily set forth in the opinion of the District Court in this case (A 197), there is no need to fully recite that history here.

Suffice it to say that on March 2, 1973, pursuant to the procedures outlined above, the FDA published an order

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(Footnote continued from previous page)

In Hynson, however, the Court went on to find, without discussion, that on the facts of the particular case, a sufficient showing had been made to require the agency to hold a hearing. 412 U.S., at 623. That decision is virtually irrelevant to the instant proceedings, particularly since appellants have chosen not to file any materials with the agency. See particularly Cooper Laboratories, Inc. v. Commissioner, FDA, 501 F.2d 772, 776-77 (D.C.Cir. 1974) discussing the impact of Hynson and the type of showing required to obtain a hearing.

denying the request for a hearing and withdrawing approval of the drug Alevaire on the grounds that the studies submitted were not adequate and well-controlled. 38 Fed. Reg. 6305. (A 20). In that notice, the agency detailed the defects it found to exist in each of the studies. Specific criticism was directed at the Miller-Paez and Cohen studies on the ground that water was not a proper control against which to test the effectiveness of Alevaire, but that the proper control was Alevaire minus its claimed active ingredient, tyloxapol. Only in this way could it be determined whether that ingredient was in fact responsible for the claims made in its behalf by the company both on the label and in the advertising of the product.

Appellants thereupon submitted rebuttal materials to the agency, requesting reconsideration in light of these materials, and simultaneously appealed from the final agency action. The FDA, upon consideration of the data, granted the petition for reconsideration and terminated its withdrawal order. 38 Fed. Reg. 15861 (A 25). Contrary to appellants' claims here, the agency did not by any stretch of the imagination thereby concede the adequacy of those studies or the effectiveness of Alevaire, as its decision upon reconsideration made abundantly clear. On August 7, 1973, pursuant to its reconsideration, the agency finally denied a hearing and withdrew approval of Alevaire, noting that:

> Even assuming that the studies are adequate and well-controlled investigations comparing Alevaire with other control substances, a conclusion not warranted by analysis of the investigations, the studies cannot demonstrate the effectiveness of Alevaire because their design precludes assessments respecting the contribution each of the three components of Alevaire makes to the claimed effectivness of the drug." 38 Fed. Reg. 21515 (A 31).

Appellants thereupon appealed from that final agency action and, when the Court of Appeals denied the agency's motion to dismiss the appeal from the March 2, 1973 order, the two cases were consolidated.

In its opinion of May 2, 1974, the Court of Appeals first dismissed the appeal from the March 2 order as moot in view of the subsequent withdrawal thereof. Then, addressing itself to the August 7th order, the Court of Appeals held that appellants had not been given proper notice of the grounds upon which the agency had ultimately relied in withdrawing approval of Alevaire and had thereby deprived appellants of an opportunity to submit evidence in support of a request for a hearing. Sterling Drug, Inc., et al. v. Weinberger, et al., 503 F.2d 675 (2d Cir. 1974). The Court then set aside the withdrawal notice and reinstated approval of Alevaire. The Court was careful to point out, however, that if the agency still intended to withdraw approval of

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Alevaire on the grounds set forth in the voided notice, it could do so, but that:

> "It must give the petitioners notice of the specific grounds proposed for withdrawal, an opportunity to present evidence showing that they are entitled to a hearing, and a hearing if that is shown to be required." 503 F.2d, at 683 (A 52).

On August 13, 1974, the agency, in accordance with this Court's direction, issued a new notice of intent to withdraw approval of Alevaire, setting forth the specific grounds on which the proposed action was based.* 39 Fed. Reg. 29013. (A 53). Appellants were thereby afforded the full thirty-day period within which to request a hearing and the full sixty-day period within which to submit evidence in support thereof. Prior to any final agency action, however, and without submitting any such evidence to the agency, appellants commenced the instant proceedings, seeking to enjoin the agency from proceeding. Despite the granting of two extensions of the time within the file evidence with the agency, appellants have yet to file any such material.

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* Following the Court of Appeals decision of May 2, 1974, appellants requested the Court to enforce their decision by, inter alia, requiring appellees "to publish notice of reinstatement of approval of the New Drug Applications for Alevaire in the Federal Register." In its opinion of October 9, 1974, the Court took notice of the August 13th order, noting it was something which the agency "was permitted to do by our decision of May 2, 1974", and declined to so order. The Court then denied the motion in its entirety. 503 F. 2d, at 683-684.

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Following the denial by the District Court of the motion for a preliminary injunction and the dismissal of their complaint for failing to exhaust administrative remedies, appellants appealed from that decision and order.

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ARGUMENT

The decision from which appellants appeal in this case held that despite the claim that the FDA proceedings are barred (a) by res judicata, collateral estoppel and estoppel by abandonment, and (b) by the agency's lack of "new information" as required by section 355(e), the complaint must be dismissed for failure to exhaust administrative remedies. Accordingly, the District Court explicitly declined to reach the merits of those contentions. (A 20).

The primary question on appeal is then the propriety of the district court's requirement that appellants exhaust their administrative remedies before seeking judicial review of their claims.* While appellants devote the bulk of their brief to the merits of the two questions which the District Judge declined to reach, the usual emphasis and arrangement of their arguments should not obscure the fact that neither of those questions need be reached here if the Court determines that the District Judge was correct in requiring exhaustion of administrative remedies.

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* 21 U.S.C. §355(h), which the District Court held to be the exclusive means by which review of such claims could be had, provides in pertinent part:

> "No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so."

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Only if the Court finds that the district court was wrong in so requiring could the court be called upon to reach the other questions which appellants raise.

POINT I

APPELLANTS MUST PRESENT THEIR CLAIMS OF RES JUDICATA/COLLATERAL ESTOPPEL AND LACK OF 'NEW INFORMATION' TO THE AGENCY ITSELF IN THE FIRST INSTANCE AND PERMIT THE AGENCY TO PASS UPON THEM BEFORE OBTAINING JUDICIAL REVIEW OF THOSE CLAIMS.

It is appellants' position before this Court that the District Court erred in requiring that they exhaust their administrative remedies because each of the claims they raise constitutes an exception to the exhaustion doctrine. First, it is claimed that one need not exhaust administrative remedies when it is alleged that the proceedings are barred by the principles of res judicata, collateral estoppel, or estoppel by abandonment. Second, it is claimed that one need not exhaust administrative remedies when it is alleged that "the agency is proceeding without statutory authority." While the Supreme Court has characterized the exhaustion doctrine as being "well established in the jurisprudence of administrative law", the Court has acknowledged that, like most judicial doctrines, it is "subject to numerous exceptions." McKart v. United States, 395 U.S. 185, 193

(1969). However, neither of the two exceptions appellants rely upon here has any basis in the prior case law. Not only are these claimed exceptions merely figmentations of appellants' pens, but when presented with an opportunity to create such exceptions in the past, the Supreme Court has unambiguously declined to do so. Perhaps more fundamentally, the creation of such exceptions in this case would run counter to the substantial interests served by the exhaustion requirement.

1. A Claim That Agency Proceedings Are Barred By The Principles Of Res Judicata, Collateral Estoppel, Or Estoppel By Abandonment Does Not Except Appellants From The Requirement That Those Claims First Be Presented To, And Determined By, The Agency.

As the government will show in the second section of its brief, the res judicata-collateral estoppel claims of appellants are based upon a fundamental misreading of the prior opinion of the Court of Appeals and a distortion of the agency's actions in granting appellants' motion for reconsideration of the March 2, 1973 order. A proper understanding of those two decisions and the case law reveals appellants' claims to border on the frivolous. Assuming for purposes of this argument, however, the validity of these claims, appellants would still not be excused from the requirement that they exhaust their administrative remedies by presenting those claims to the agency in the first instance.

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As noted by the Supreme Court in McKart, "the long-settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted", enunciated in Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51 (1938), has been subject to several exceptions in the intervening years. On three different occasions, however, federal courts have been afforded an opportunity to carve out such an exception to the exhaustion requirement where a claim of res judicata is raised, and on each occasion, the court declined to do so.

In Coca-Cola Company v. F.T.C., 475 F.2d 299 (5th Cir.), cert. denied, 414 U.S. 877 (1973), soft drink manufacturers and bottlers involved in unfair competition proceedings before the FTC sought to enjoin that agency from proceeding unless there was joinder of certain parties claimed to be indispensable to the litigation. The Court of Appeals, after reviewing the statutory provisions providing for judicial review exclusively in the Court of Appeals following final agency action, held that judicial review of the interlocutory agency decision denying joinder was improper and affirmed the District Court's dismissal of the case.

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The court surveyed the exceptions to the exhaustion requirement and found that none was applicable in light of the claims raised by the plaintiffs. Specifically, the court noted, it was claimed that "if the proceedings before the Commission continued and FTC prevails, the Companies will be subject to two inconsistent decrees," namely, the ensuing Commission order and a consent decree entered by a District Court in 1920 in another case. The court responded unequivocally that:

> "A contention of res judicata is not cognizable by courts until administrative proceedings are at an end, S.E.C. v. Otis & Co., 338 U.S. 843 (citations omitted) (1949), and we intimate no view as to the merits of this contention." 475 F.2d, at 304.*

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* The court then went on to observe that the extraordinary remedy of judicial intervention in agency proceedings still in progress is unavailable unless necessary to vindicate an "unambiguous statutory or constitutional right", and not simply to secure some equitable right "to be free from defending a multiplicity of law suits."

> To adopt the plaintiffs' position . . . would be to make a rule that judicial intervention to "correct" an interlocutory agency ruling is available wherever an agency ruling differed from some equitable maxim." 475 F.2d, at 304.

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Appellants attempt to avoid the thrust of this decision claiming that "There was no clear res judicata issue", since plaintiffs there were claiming only that there might be res judicata problems in the future." (Brief at 51) It was, however, that potential res judicata problem which was the basis for plaintiff's claim that exhaustion should not be required. The court held not that the mere potentiality of the res judicata problem rendered it unexceptable from the exhaustion requirement, but rather that a claim of res judicata and the burden which breach of that principle would impose on plaintiffs were not a permissible basis upon which to except plaintiffs from the exhaustion requirement.

In Petro v. Bakely, 353 F.2d 511, 512 (3rd Cir. 1965), the Court of Appeals held that "an order of the district court denying a defendant's motion to dismiss as res judicata an action for negligent injury . . . lacks the finality which is essential to support an immediate appeal." Appellants seek to distinguish this case by arguing that (a) the res judicata claim was raised "in a negligence action involving no administrative agency", and (b) defendant there failed to seek certification of the issue under 28 U.S.C. §1292, in which event, they claim, review would have been ordered. While there is little question that the proceedings in Petro were judicial and not administrative, the case clearly holds that

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the assertion of a claim of res judicata does not exempt the claimant from the requirement of judicial exhaustion pending appellate review, and the principles underlying both the judicial and administrative exhaustion doctrines are substantially the same. McKart v. United States, supra, at 194. Indeed, the appellant in Petro was in a stronger position to argue for exemption from the exhaustion requirement than appellants here since in Petro he had first raised the res judicata claim before the trial court and received an adverse determination thereupon. As for the highly speculative certification argument raised by appellants, they have not cited a single case in which certification of a res judicata claim has been ordered, much less any cases in which such claims have been excepted from the exhaustion requirement.

Finally, and most authoritatively, the Supreme Court's action in summarily reversing a lower court decision excusing res judicata claimants from the exhaustion requirements, in S.E.C. v. Otis & Co., 338 U.S. 843 (1949), reversing Otis & Co. v. S.E.C., 176 F.2d 34 (CA DC 1949), is dispositive of the very claims appellants raise before this court, and unless that decision is rejected by this Court, would appear to foreclose the need for further inquiry on this point. The case is factually complex and requires close scrutiny particularly since appellants' strained attempts to distinguish it have substantially

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muddied the waters.

In that case, Otis & Co. had cancelled an agreement to purchase an issue of common stock on the grounds that litigation was brought against the issuing company the day of the closing, and the absence of such litigation was a condition precedent to the underwriting agreement. It was alleged by the issuing company in a private action that the suit had been instituted by two attorneys acting at the request of Otis or its principal stockholder, Cyrus Eaton. The Securities and Exchange Commission instituted a public investigation for possible violations of the anti-fraud provisions of the 1934 Act.* During the course of this investigation, the agency subpoenaed the two attorneys who testified as to their client's name only after being ordered to do so by the District Court. They refused, however, to testify concerning the communications between them and Eaton on grounds of attorney-client privilege. The SEC then sought an order from the District Court compelling them to testify to those communications, on grounds that the privilege was pierced by the agency's prima facie showing that Eaton had consulted the attorneys concerning the perpetuation of a fraud. The District Court,

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* Appellants attempt to distinguish this case in part on the grounds that the SEC had conducted only a "private investigation" during which the attorneys had refused to testify. Although we fail to see its relevance, it must be noted that the agency did not call the attorneys until it had instituted a "public investigation", at which time "extensive hearings were conducted." 176 F.2d, at 35.

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however, found that the evidence adduced by the SEC did not constitute the requisite prima facie showing of fraud required to pierce the privilege, and declined to compel the witnesses to testify.

While the case was pending before the District Court, however, the SEC commenced a proceeding against Otis to revoke its broker-dealer registration on the ground that, as a result of the public investigation, the Commission had obtained information which, if true, showed that Otis had inspired the fraudulent suit. Those proceedings were stayed pending the decision on the motion to compel testimony, but, following the District Court's denial of that motion on October 28, 1948, Otis sued the SEC in District Court, seeking to enjoin its proceedings insofar as they related to the instigation of the allegedly fraudulent suit, on the grounds that:

> "the judgment of this Court of October 28, 1948, is binding as res judicata on the defendant Commission and that it is without power to conduct the proposed inquiry into the alleged instigation of the Masterton suit." 176 F.2d, at 37.

The complaint went on to recite that "The Commission does not have and cannot produce any evidence in addition to that in the record . . . which has heretofore been passed upon by this Court," and found not to constitute even a

prima facie showing of fraud. Id.

The District Court dismissed the complaint. Although the Court of Appeals opinion does not indicate the basis for the District Court's decision, the briefs which the parties subsequently submitted to the Supreme Court on petition for certiorari reveal that the same District Judge who had found the evidence insufficient to constitute a prima facie showing of fraudulent purpose heard this subsequent case and dismissed the complaint from the bench on the grounds (1) that he had never undertaken to decide the ultimate question of fraud vel non in the subpoena action, and (2) "that the doctrine of Myers v. Bethlehem Shipbuilding Company, 303 U.S. 41, required the plaintiff to exhaust its administrative remedies before obtaining judicial review, which could be done in the proper court of appeals pursuant to the statute, if the Commission's final order was adverse (R 65-67)." (Brief of the Solicitor General on Petition for Writ of Certiorari, at 8, in S.E.C. v. Otis & Co., 338 U.S. 843 (1949)).

The Court of Appeals reversed the District Court on the exact theory urged by appellants in this Court. It found that "the Commission is about to examine the identical issue considered by the court with respect to the alleged fraud", and held that the doctrine of res judicata applied to bar the agency from thus proceeding. It then turned its attention to the SEC's claim, and the District Court's holding, that under Myers v. Bethlehem Shipbuilding

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Company, the court lacked jurisdiction to entertain the suit for failure to exhaust administrative remedies. In unambiguous language, almost identical to that of appellants, the Court distinguished Myers and Oklahoma Press Publishing Company v. Walling, 327 U.S. 186 (1946), by noting that:

> In neither of them was the doctrine of res judicata involved. In neither had there been a previous determination by a court of competent jurisdiction of the issue which the administrative agency was about to consider and decide. Those cases do not support the Commission's contention that an injunction may not be issued in the instant case because it would interrupt the hearing at the threshold, which may not be done under the principle that the administrative process must be completed before recourse can be had to a reviewing court. This is not the threshold of the administrative process, because the evidence has already been heard and the Commission has already announced its conclusion therefrom. The Commission's only possible purpose in desiring to reconsider the record, which has already been construed in one way by the Commission and later in the opposite way by the court, is to reverse the decision of the court. (emphasis supplied) 176 F.2d, at 42.

The Court of Appeals then ordered the case remanded to the District Court with the direction that the agency be enjoined from proceeding on that issue unless it could show that it intended to introduce additional evidence

so as to be relieved of the bar of res judicata.

The Supreme Court granted certiorari and summarily reversed, citing Myers v. Bethlehem Shipbuilding, supra, Macauley v. Waterman S.S. Corp., 327 U.S. 540 (1946), and Federal Power Commission v. Arkansas Power & Light Co., 330 U.S. 802 (1947). It is difficult to imagine a more forceful or indeed more authoritative rejection of the position appellants urge before this Court than this action by the Supreme Court. It is the government's position that the decision in S.E.C. v. Otis & Co. is controlling in this case and fully disposes of appellants' claims.

Appellants strain to avoid the logical consequence of that holding by offering three perfunctory and clearly untenable arguments. First, they claim "it is quite conceivable that the Supreme Court felt that a bar of the entire proceeding on those facts was simply too drastic and that the Commission should be given the opportunity in its own proceeding to show independent evidence of fraud." (Brief at 49) Aside from its irrelevance, had this been the Supreme Court's intent, it would have affirmed rather than reversed the Court of Appeals since the latter's order had expressly provided for precisely that opportunity. 176 F.2d, at 44.

Second, appellants then claim that "the equitable compulsion to apply the doctrine of res judicta was far less

there, where it was not at all clear that Otis' rights would be infringed, than here, where the relitigation will be of the exact same issue in the same kind of proceeding." (Brief at 50). This specious argument ignores the fact that the Court of Appeals had found that the agency proposed to relitigate the precise issue determined previously. More fundamentally, it ignores the fact that it was not the application of the res judicata doctrine which the Supreme Court rejected but the failure to require exhaustion of administrative remedies as evidenced by the citation of Myers, etc.

Finally, appellants claim, almost unbelievably, that the Supreme Court's action in Otis is not controlling here because "none of the cases cited in [its] per curiam reversal . . . involved issues of res judicata." (Brief at 51). This claim, while true, proves nothing more than that the Court had not previously decided the precise issue. All three cases were instances in which courts found exhaustion of administrative remedies to be required and the citation of those cases by the Supreme Court in Otis is thus a holding that exhaustion is required where claims of res judicata are raised as well.*

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* In fact, the three cases cited were all cited in the Solicitor General's brief in support of the proposition that "The decision below is thus inconsistent with the doctrines as to primary jurisdiction and the exhaustion of administrative remedies. . . ." (Brief at 11).

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An examination of the briefs submitted to the Supreme Court again reveals that the question before this court was squarely before the Supreme Court in Otis and was decided adversely to the position appellants urge here. In its specification of errors, after challenging the Court of Appeals' finding that the two proceedings were res judicata, the Solicitor General claimed that the court erred

> "If it be assumed that the doctrine of res judicata is applicable, in enjoining the administrative proceeding rather than allowing the defense of res judicata to be raised in due course during the administrative and judicial proceedings prescribed by the statute." (Brief at 10).

It is thus apparent that the claim raised by appellants before this Court, namely that an allegation that agency proceedings are barred by res judicata is an exception to the exhaustion requirement, has been presented to and rejected by the Supreme Court itself, as well as two lower federal courts. As Professor Davis succinctly described the holding in S.E.C. v. Otis, "[t]he Supreme Court reversed per curiam on the ground of failure to exhaust administrative remedies." K. Davis. Administrative Law Treatise, Vol. III §20.05, at 85-86.

While no more need be said on this question, it bears mention, in view of appellants' claims, that aside from the weight of the case law, the interests underlying the exhaustion doctrine are substantially furthered by requiring adherence to that rule in this case.

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As stated in McKart, among the purposes served by the doctrine is the avoidance of premature interruption of the administrative process both to allow the agency to develop the necessary factual record, and to allow the agency a chance to first exercise its discretion or apply its expertise. 395 U.S., at 193-194. In addition, the doctrine advances the general interests of administrative and judicial efficiency by the avoidance of piecemeal reviews. See Diapulse Corporation of America v. F.D.A., 500 F.2d 75 (2nd Cir. 1974).

It is certain that if this Court were to hold a claim of res judicata to constitute an exception to the exhaustion requirement, in any case where such a claim could be made out without embarassment, it would be done in order to delay proposed adverse agency action. Administrative proceedings would be interrupted and delayed indefinitely. Following a trial on the question of res judicata and, as in this case, the factual circumstances of appellants' abandonment claim, the decision in the District Court would presumably be appealed, thus posing the likelihood of still further long delays. Moreover, the number and scope of the ancillary res judicata claims that may arise in such proceedings are limitless, each requiring similar lengthy proceedings and attendant interruption of the agency process.

Appellants argue, however, that they should be excepted from this exhaustion requirement because "it will

be futile to submit this issue to the Agency" since "defendants have made it very clear that they do not consider themselves barred from relitigating the previously abandoned issue." (Brief at 44) While there is a judicially recognized exception to the exhaustion doctrine where the remedies themselves would be futile, see Steele v. Louisville & Nashville R. Co., 323 U.S. 192 (1944); Vaca v. Sipes, 386 U.S. 171 (1967),* the agency's view that it is not barred from proceeding is not the type of futility against which the doctrine is directed.

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* The "futility" exception to the exhaustion requirement which appellants seek to bring themselves within originated with the Supreme Court's decision in Steele v. Louisville & Nashville R. Co., supra, and was developed in its progeny including Glover. In those cases, the Court held that employees alleging racial discrimination were not required to submit their claims to the very group against whom those claims were directed, namely the union itself or, on occasion, an employer. These cases and the non-racial claims cases following this decision, see Vaca v. Sipes, supra, all appear to have involved submission of claims to a private entity, rather than a public agency such as the FDA. Thus, in Brown v. G.S.A., Slip Op. 5919 (2nd Cir. November 21, 1974), this Court did not except appellant from the exhaustion doctrine in a case involving claims of racial discrimination in employment where further recourse could be had before public agencies. Slip Op. at 5933-34. Moreover, even in Glover, on which appellant relies, the Court required and found an attempt to exhaust contractual remedies. 393 U.S., at 331.

The "futility" exception has apparently been applied to proceedings before a public agency principally when that agency did not have the power or authority to grant the relief sought, i.e., when it was not an "adequate" remedy, as noted in Glover. This is clearly not the case here. See also McNeese v. Board of Education, 373 U.S. 668 (1963); Eisen v. Eastman, 421 F.2d 560, 567-69 (CA 2 1969).

In this respect, appellants stand on no different ground than anyone claiming <u>any</u> proposed agency action to be illegal, for in all such cases the agency might well proceed in spite of those claims, and indeed most certainly where the agency has not even been presented with them.* If no more were required than this to excuse one from exhausting administrative remedies, it

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* Indeed, it must not be forgotten that the FDA has in fact <u>never</u> been presented with nor permitted to comment upon either the res judicata or "new information" arguments which appellants raised before the District Court.

is certain that this "exception" would swallow the rule, with substantial damage to the Congresionally established administrative scheme occurring. Accordingly, with few exceptions, courts continue to require that where Congress has enacted a specific statutory scheme for obtaining review, that statutory mode of review be adhered to. In this case, 21 U.S.C. §355(h) specifically provides that:

> "No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so."

Appellants also claim that it would be useless to require exhaustion here in any event because the agency cannot exercise its expertise since the questions which they raise are legal issues only. Again, as the District Court recognized, in claiming that the agency is acting in violation of law, appellants stand in no different posture than one raising any legal challenge to any agency's proceedings.

> "Perforce the claim in every suit of this type is that the administrative agency is acting illegally. If a court without more were to rule on the merits of each such claim this would undermine basic administrative law procedures and thereby promote the very piecemeal litigation which the doctrine in part aims to discourage. (A 205)

Furthermore, appellants' argument that the agency can exercise no expertise as to questions of law runs counter to the statutory and regulatory scheme which explicitly provides that legal questions as to the status of a particular drug product shall be raised before the agency in response to the notice of opportunity for hearing or shall be deemed waived. 21 C.F.R. §314.200(e). The August 13th notice did thus inform appellants.

While the bulk of such legal issues typically would involve questions of whether the Act applied to a new product and the like, and thus perhaps be thought to draw upon the agency's experience in handling only those particular types of legal issues, submission of the issues appellants raise here be of at least as much value. Thus, doing so would permit the agency to draw upon its legal expertise in interpreting the "new information" requirement, or in the case of the res judicata claims, its knowledge of its own procedures, generally, and the actions it has taken in this case in particular. Under present practice, the

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agency would have been required, if it found the claims unmeritorious, to respond fully, giving its reasons for rejecting each of the various claims raised.* (See e.g., agency response to legal arguments in the March order (A 23)). It was precisely to insure that the opportunity to establish such a record is preserved that the exhaustion doctrine was fashioned. McKart v. United States, 395 U.S., at 193.

Finally, appellants seek to salvage their claim of exception from the exhaustion requirement by falling back on the now repeatedly-rejected argument that "If plaintiffs are forced to submit to the administrative process, it may be years before they are able to return to this Court to seek a ruling on the issue of res judicata." (Brief at 45). This claim was implicitly rejected by the Supreme Court in Otis when the Court required respondents there to go through those administrative proceedings

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* Even in Diapulse Corporation v. Commissioner, FDA, 500 F.2d 75 (2d Cir. 1974) on which appellants rely, this Court was careful to point out that in part, exhaustion was not required there not simply because the claims were "legal" in nature (involving a question under the Freedom of Information Act) but because "we are presented with a legal question on which the Commissioner of the FDA has already issued his opinion." 500 F.2d, at 78. Appellants there were excused from resorting to appellate procedures, within the agency in view of that and more importantly, the fact that the Court found neither side knew of the recent regulatory amendments making further review possible. Id.

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before bringing their res judicata claims to the courts.* This claim has been raised and rejected in almost every case where a court has declined to excuse a litigant from the exhaustion requirement. See Pepsico, Inc. v. F.T.C., 472 F.2d 179, 187 (2d Cir. 1972); Bristol-Myers Co. v. F.T.C., 469 F.2d 1116, 1118 (2d Cir. 1972); Frito-Lay, Inc. v. F.T.C., 380 F.2d 8 (5th Cir. 1967). As the District Court properly observed, the possibility that such a procedure may require appellants to expend additional time, money and effort in further contesting the withdrawal proposal is not a sufficient basis for allowing them to circumvent the proper administrative channels. (A 207). See Sampson v. Murray, 415 U.S. 61, 89-92 (1973); Renegotiation Board v. Bannercraft Co., [illegible] U.S. 1, 24 (1973). As the court in Coca-Cola Company v. F.T.C., supra at 304, sagaciously observed:

> "If plaintiffs eventually prevail on review of the final order and it is necessary to begin anew with Commission proceedings, it will not be the first

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* In fact, respondents in Otis argued in almost identical language in their Petition for Reconsideration, which was also denied:

> We intended to show the abuse, the injury and the intolerable burden of oppression which would result in the present case from permitting relitigation of issues already concluded. We intended to show the evil that would follow from remitting us to a hearing before the SEC, to years of litigation and expense, perhaps only at the end to face again in this Court the res judicata question, which the Court did not pass on in its summary reversal." (Petition at 4)

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time events have taken that course."*

In conclusion, it appears settled that where Congress has provided a specific statutory scheme providing for judicial review of administrative action, even the assertion that the agency proceedings are themselves barred by res judicata/collateral estoppel must first be presented to the agency for its consideration and the statutory remedies thereby exhausted before seeking judicial review, under decisions of the federal courts and in furtherance of the substantial judicial and administrative interests served by the exhaustion doctrine.

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* The Supreme Court itself observed in response to similar claims of onerousness in Myers v. Bethlehem Shipbuilding:

> "Lawsuits also often prove to have been groundless; but no way has been discovered of relieving a defendant from the necessity of a trial to establish that fact."
> 303 U.S., at 51-52.

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2. A Claim That The Agency Lacks "New Information" As Required Under 21 USC §355(e) And Is Therefore Proceeding Illegally, Does Not Except Appellants From The Requirement That The Claim First Be Presented To And Determined By The Agency

As in the case of appellants' res judicata claim, an examination of their "new information" claim contained in the third section of this brief reveals it to be groundless. Assuming once again for purposes of this argument the validity of this claim, however, appellants would still not be excused from the requirement that they exhaust their administrative remedies with respect thereto.

Appellants' position is that the agency lacks "new information" that Alevaire is ineffective, which section 355(e) requires it to possess before proceeding to withdraw approval of the drug. This is allegedly so because (a) the NAS-NRC study upon which the agency relies has been the subject of litigation which was resolved in favor of the plaintiff," (A 166) and in any event the report fails to demonstrate Alevaire to be a fixed combination drug, and (b) the labeling information on which the agency relies is incorrect (Brief at 40). Lacking such new information, appellants claim that "the agency is proceeding in violation of its statutory authority," (Brief at 53)

and therefore, there is no need to exhaust administrative remedies.

Once again, appellants find it necessary to do substantial violence to the case law in order to find legal authority for their novel position, and they totally fail to perceive the very substantial interests served by requiring exhaustion of questions such as their "new information" claim, which so directly involves an exercise of of agency expertise.

The mere assertion that an agency is acting in violation of its statutory authority, standing alone, has generally been deemed insufficient to excuse a litigant from the exhaustion requirement. To permit such claimants to proceed directly to court upon such allegations would, as the District Court noted, mean such review could be had in virtually every case and would defeat the substantial interests in the avoidance of piecemeal litigation and the expeditious completion of agency processes furthered by the exhaustion requirement. Accordingly, it is only where it is alleged that the agency has acted in direct violation of an express statutory prohibition or command that courts have recognized an exception to the exhaustion requirement. The source of this exception is the Supreme Court's decision in Leedom v. Kyne, 358 U.S. 184 (1958), but even a

superficial reading of that case reveals that it differs fundamentally from the case at hand.

In Leedom v. Kyne, the NLRB was alleged to have violated section 9(b)(1) of the National Labor Relations Act, which required that in determining the appropriate unit for collective bargaining purposes "the Board shall not (1) decide that any unit is appropriate for such purposes if such unit includes both professional employees and employees who are not professional employees unless a majority of such professional employees vote for inclusion in such unit." (emphasis supplied). Despite the express statutory prohibition (except upon a precisely-stated condition), the NLRB first refused to take a vote among the professional employees to determine if they would vote for inclusion, and then included both professional and non-professional employees in the bargaining unit in direct violation of the statute.

A reading of the decision reveals three factors which the supreme Court found to require excusing the aggrieved employees in the case from exhausting their administrative remedies. While the Court has never made clear what number or combination of these factors must be present to permit exception from such a requirement in the future, a comparison of the Supreme Court's careful decision in that

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case and the facts of this case reveal that none of those factors is present here.

In Kyne the statutory command was found to be express and mandatory, and the NLRB did not even claim that it had not violated that unambiguous prohibition.* In this case, on the other hand, while the statute does require that the agency have "new information," the determination of whether the agency possesses such material (a) is the subject

* Jewel Companies, Inc. v. FTC, 432 F.2d 1155 (7th Cir. 1970) on which appellants rely also involved a straight-forward question of statutory construction (whether or not the statute provided the Commissioners discretion to consider the public interest in deciding whether to issue a complaint), and is for that reason alone distinguishable. When called upon to determine whether, as a matter of law, the complaint charged a violation of the Robinson-Parman Act, the Court explicitly declined to do so, requiring presentation of that claim to the agency. 432 F.2d, at 1159. The Court also found that immediate review of the particular issue noted was required because the different standard which would govern the issue on review would effectively deprive appellants of an adequate remedy.

In Elmo Division of Drive-X Company v. Dixon, 348 F.2d 342 (D.C. Cir. 1965) the court excused appellants from exhausting their administrative remedies in an action seeking to enjoin the FTC from continuing with complaint proceedings against them on grounds that a consent decree entered in an earlier proceeding provided that the only way in which the FTC could again proceed against the agency was by way of reopening that original case. The court, however, based its decision squarely on its conclusion that "District Court jurisdiction...is appellant's only effective remedy." 348 F.2d, at 344. The court explained at length that the statutory provisions had the same practical effect as the mandatory language of the statute in Leedom v. Kyne and noted that the parties had "put a construction upon the statute which renders it directive of such a nature." Id. at 345 and n. 4. The vigorous dissent is sharply critical of even this reliance on Leedom v. Kyne, Id. at 348-49.

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of substantial dispute between the parties, and (b) requires scrutiny of the evidence presented to determine whether it is "new" and whether it is probative as to lack of effectiveness. The task of determining the adequacy of the information on which the agency relies is thus one which would be substantially assisted by application of the agency's particular expertise. Congress recognized the particular relevance of an administrative record when it provided that the agency and not the courts would determine, in the first instance, whether there is a lack of substantial evidence of effectiveness or whether the evidence before the agency demonstrates effectiveness. As the Court of Appeals recognized in its May 2 decision in responding to the claim that the record did not support treatment of Alevaire as a fixed combination drug:

> "While there is little in the record now before us to support the proposition that Alevaire is affixed combination drug within the meaning of 21 C.F.R. 3.86, it is not for this Court to pass on the question on this appeal."

Rather, after the agency followed the proper notice requirements,

> "The FDA may then determine the question on a full and proper record, subject, of course, to petitioners' right of appeal to this Court from an adverse determination."
> 503 F.2d, at 683 (A 52)

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In a similar vein, the District Court recognized that:

> Whether the agency does in fact possess "new information" to support its conclusion is a factual determination which should first be made by the FDA. Contrary to plaintiffs' argument, this issue does not present a straightforward question of statutory construction as in Jewel Companies, Inc., v. FTC, 432 F.2d 1155 (7th Cir. 1970). It is incontrovertible that the FDA has before it reports and other data dealing with the effectiveness of Alevaire. Whether an assessment of this data will justify treatment of the drug as a fixed-combination drug is a question which should first be decided by the FDA. Only after this determination is made and it then becomes clear on what specific information the agency has relied for its conclusion can a court determine whether the data used constitutes "new information..."[T]he FDA should first be given the opportunity to decide the question on a full and proper record. (A 208) (emphasis supplied)

It is apparent then that the new information provision at issue here is not the type of express and mandatory direction to the agency which was involved in Leedom v. Kyne, but rather is one as to which it is vital to have the agency's views upon a "full and proper record." In fact, it would be difficult to think of an issue that

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more directly implicates the exhaustion doctrine as outlined in McKart than this issue, going as it does to the very core of the agency's function.

The second factor relied upon by the Court in Leedom v. Kyne was that the NLRB, by its action, had deprived the aggrieved employees of a specific "'right' assured them by Congress." 358 U.S., at 189. Appellants here face no loss of such a right, but rather face only the potential loss of time and money required in proceeding before the agency assuming that upon completion, the FDA were found to have lacked new information. Such a loss has never been thought to rise to the level of a right, Coca-Cola v. FTC, supra, at 304, and has been explicitly rejected as a permissable basis upon which to excuse appellants from the exhaustion requirement. Myers v. Bethlehem Shipbuilding, supra, at 51-52.

Appellants seek to invoke the benefit of this Court's observation in Pepsico, Inc. v. FTC, supra, at 187, that:

> [W]e shall accept for the sake of argument, despite possible contrary implications from the per curiam in Arkansas Power & Light Co. v. F.P.C., 330 U.S. 802, 67 S. Ct. 963, 91 L.Ed. 1261 (1947), rev'd 81 U.S. App. D.C. 178, 156 F.2d 821 91946), see also Bristol-Myers Company v. FTC, 469 F.2d 1116 (2 Cir. 1972) that we can extrapolate from cases such as Leedom v. Kyne, 358 U.S. 184, 79 S. Ct. 180, 3 L.Ed. 2d 110 (1958), and McCulloch v. Sociedad Nacional de Marineros, 372 U.S. 10, 83 S.Ct. 671, 9 L.Ed. 2d 547 (1963), a principle that one can find "final agency action for which there is no other adequate remedy in a court" if

> an agency refuses to dismiss a proceeding that is plainly beyond its jurisdiction as a matter of law or is being conducted in a manner that cannot result in a valid order.

Judge Friendly was, however, careful to point out that by this principle,

> The injury against which a court would protect is not merely the expense to the plaintiff of defending in the administrative proceeding, which Myers held not to be enough, 303 U.S. at 51-52, 58 S.Ct. 459, but, in a case like this, the enormous waste of governmental resources and the continuing threat of a complete restructuring of an industry.

Obviously, no injury even approaching that magnitude is threatened here, and appellants cannot bring themselves within that "possibly over-generous principle." Id.

Finally, the Court in Leedom v. Kyne noted that a failure to find jurisdiction in that case would have meant "a sacrifice or obliteration" of that Congressionally-created right. The Court, however, did not mean simply that the employees wolud lose their rights until final review occurred which is what appellants here claim, but that review itself would be foreclosed since no other review was provided to those employees by statute, 358 U.S., at 190.* Thus, the

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* Under the National Labor Relations Act, the claims of these aggrieved professional employees within the union could be reviewed only if the employer chose to challenge the certification procedures by refusing to bargain with the union, thereby causing unfair labor practice proceedings to be commenced.

exception in Leedom v. Kyne was in part necessary to provide review of claims which would otherwise ultimately elude review altogether. Here, there is obviously no such problem since section 355(h) provides for review of all aspects of the Commission's proceeding upon appellant's petition. If such review revealed the agency to have proceeded impermissably, the entire proceedings would be set aside.

The agency has not engaged in "an exercise of power that has been specifically withheld," 358 U.S., at 189, and appellants cannot invoke the exception carved out in Leedom v. Kyne or its progeny. Moreover, each and every interest underlying the exhaustion doctrine as outlined in McKart militates against creating such an exception in this case.

3. A General Allegation of Denial of Due Process Rights Does Not Excuse Appellants From Exhausting Their Administrative Remedies

Finally, appellants seek shelter in the exception to the exhaustion requirement carved out by this Court in Fay v. Douds, 172 F.2d 720, 723 (2nd Cir. 1949) by claiming that the agency is acting "arbitrarily and without authority, and in so doing is damaging plaintiffs' valuable property rights in their license and product," thereby "violating the Due Process guaranteed plaintiffs by the Fifth Amendment." (Brief at 54). In Fay v. Douds, the Court found that the assertion of constitutional right" might give a court

jurisdiction to entertain certain claims without exhaustion, but went on to qualify that general rule by requiring that the assertion not be "transparently frivolous," or "plainly untenable." Despite the fact that appellants' complaint (A 4) made no such claim whatsoever, the District Court explicitly found that the requisite showing of such a violation had not been made. (A 211).

As another circuit has aptly observed, the "fact that the attack is voiced in conclusory language of a denial of due process and like constitutional rights does not warrant stopping... [an administrative agency] in its tracks." Bokat v. Tidewater Equipment Co., 363 F.2d 667, 672 (5th Cir. 1966). Similarly, the District Court in Pepsico, Inc. v. FTC, 343 F. Supp. 396, 399 (S.D.N.Y. 1972) required a showing that the "agency has very clearly violated an important constitutional right."

While the lack of specificity in appellants' claim alone justifies a court in declining to decide those claims at the present time, the statutory procedures for presentation of appellants' claims to the agency and for judicial review of agency action and the particular actions of the agency in this case comport fully with the requirements of Due Process and deprive appellants of no constitutional rights.

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In conclusion, it would appear that where Congress has provided an adequate procedure for judicial review of administrative action, that procedure must be followed. "Only in extraordinary cases will parties be allowed to deviate from this statutory course and seek injunctive relief from the district court, short-circuiting the administrative procedure." Coca-Cola v. FTC, 342 F. Supp. 670, 675 (N.D. Ga.), aff'd 475 F.2d 299 (5th Cir. 1973). Based upon the foregoing, we would submit that this is not such a case.

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POINT II

EVEN ASSUMING ARGUENDO THAT APPELLANTS CAN RAISE THEIR RES JUDICATA/COLLATERAL ESTOPPEL/ABANDONMENT CLAIM PRIOR TO EXHAUSTING THEIR ADMINISTRATIVE REMEDIES, NONE OF THOSE PRINCIPLES APPLIES AND THE AGENCY IS NOT BARRED FROM PROCEEDING

In its order of March 2, 1973, withdrawing approval of Alevaire, the FDA examined each study submitted by appellants in support of their claims of effectiveness, and found each to be inadequate. In the case of the Miller-Paez and Cohen studies on which appellants had principally relied, the FDA found those studies to be deficient in two respects. First, the agency felt that the studies "did not compare Alevaire to a proper control, e.g. Alevaire minus tyloxapol" but only compared it to water or saline solution. (38 Fed. Reg. 6307)(A.22). The agency's concern was that any claims made on behalf of the active ingredient Alevaire might in fact have resulted simply from the vehicle solution in which it was contained, a solution of 2% sodium bicarbonate, 5% glycerine, and 93% water, and the failure to test tyloxapol against that solution precluded any assessment of tyloxapol's true effectiveness.

The second respect in which the agency felt the studies to be inadequate consisted of a host of procedural defects in the studies which the agency enumerated in the

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March order.*

Appellants' motion for reconsideration pointed up several respects in which these claimed technical deficiencies were incorrect.** In addition, affidavits were submitted to indicate that water or saline were proper controls against which to test tyloxapol. The agency felt that enough of its technical criticisms were called into question to justify reconsideration of the request for a hearing and the evidence submitted in support thereof, and so

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* In the case of the Cohen study, for example, the March order noted that:

> This test is not an adequate and well-controlled study since the diagnostic criteria for identifying bronchial asthma and chronic bronchitis patients were not stated as required by 21 C.F.R. 130.12(a)(5)(ii)(a)(2), the method of patient selection is not explained, the study did not state the steps taken to assess subjective response and minimize bias on the part of the subject and observer . . ., the test did not document the levels and method of blinding . . ., and the administration of the water and Alevaire was preceded by the inhalation of a bronchodilator, meaning the effects of water and Alevaire cannot be separated from the effects of the bronchodilator. (A 22).

Numerous deficiencies were found in the Miller-Paez study as well (A 22).

** Illustrative of these deficiencies was the fact that although the Cohen study did not state the diagnostic criteria for identifying bronchial asthma and chronic bronchitis patients, as the agency stated, the pages did contain a footnote to a publication containing diagnostic criteria which were apparently used to select patients, as appellants made clear in their motion for reconsideration. (A 176, 177).

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appellants' motion was granted and the withdrawal notice revoked. 38 Fed. Reg. 15861 (A 25).

Upon reconsideration, the FDA issued its August 7th order, again denying a hearing and withdrawing approval. Upon an extensive evaluation of the claims made on behalf of the various ingredients in Alevaire in the labelling and advertising of the product conducted by the agency in the interim, the agency felt it to be a fixed-combination drug within the meaning of 21 CFR §3.86,* and the order explained at length the basis for its conclusion. 38 Fed. Reg. 21515 (A 28-31). Accordingly, the agency felt the Miller-Paez and Cohen studies to be inadequate to demonstrate effectiveness because they did not test each of the active ingredients against the various combinations of the other ingredients as required by Section 3.86, but only against water and saline solutions.**

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* 21 C.F.R. §3.86 provides that a fixed combination drug consists of two or more drugs combined in a fixed ratio in a single dosage form where each component makes a contribution to the claimed effects of the drug. The required format of studies which must be conducted to demonstrate the effectiveness of such drugs are fully described in 21 C.F.R. §314.111 and §3.86 as well.

** Indeed, the only study the agency found which tested Alevaire against its vehicle solution, the Palmer Study, demonstrated that it was no more effective than the control solution containing sodium bicarbonate but no detergent, as the agency noted in its March and August orders. (A 24, 33).

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Contrary to appellants' repeated claim that by its revocation of the March order the agency had conceded that the two studies were adequate and well-controlled, the agency was careful to indicate it felt these studies were improperly conducted in addition to being inadequate to demonstrate effectiveness. As the agency pointedly noted:

> Even assuming that the studies are adequate and well-controlled investigations comparing Alevaire with other control substances, a conclusion not warranted by analysis of the investigations, the studies cannot demonstrate the effectiveness of Alvaire because their design precludes assessments respecting the contribution each of the three components of Alevaire makes to the claimed effectiveness of the drug."* (A 31).

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* Appellants also attempted to argue that counsel for the agency conceded the adequacy of the studies in its briefs and at oral argument before the Court on February 1, 1973. (Brief at 28, A 196). Following the hearing on October 10, 1974, the government indicated to the court its preparedness to submit affidavits from the attorneys who argued the appeal that nothing of the sort was said at oral argument, and suggested that the court listen to the tape of the argument. (A 212-213). An examination of the brief submitted by the agency on that appeal makes it abundantly clear that no such concession could have been made, for in that brief, the agency noted the many defects contained in the studies, and argued that those studies were irrelevant in any case because they did not properly test Alevaire as a fixed-combination drug. See Respondents' Brief on Petition to Set Aside, Docket Nos. 73-1628 and 73-2481, at 6 which states:

> "Notwithstanding the inability of Drs. Cohen and Miller to justify this crucial design fault in their studies, they did pinpoint several real defects in the March order."

As noted, the August 7th order reiterated both the agency's criticisms of those studies.

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Upon review of the agency's action in its May 2, 1974 decision, the Court of Appeals expressly declined to pass on the March order, noting that it had since been revoked and hence that no further relief was possible. The Court accordingly dismissed the appeal from that order. (A 44).

With respect to the August 7th order, the Court of Appeals looked at the theory upon which the agency had relied in ultimately withdrawing approval of Alevaire (the fixed-combination theory) and at the theory upon which it had based its initial notice of intent to withdraw approval in its December 1969 notice (the single-entity theory) and found that by this change in theories, the agency had deprived appellants of proper notice of the grounds upon which it ultimately relied in withdrawing approval and of the opportunity to submit evidence in support of their request for a hearing, and concluded that the order had to be set aside. 503 F.2d, at 682. (A 48-49). By no stretch of the imagination did this Court pass upon the adequacy of the data submitted or the agency's position with respect to that data.

Appellants argued at length in the District Court that by its May decision, this Court had affirmatively found the two studies to have been proper and sufficient to demonstrate Alevaire's effectiveness, and that accordingly,

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the agency was barred from proceeding on the single-entity theory by res judicata.* (A 9, 11, 12, [Complaint]; A 165, 166, 169, 174). This claim was met with considerable skepticism both from the District Judge (A 169, 173) and from the members of the panel which heard appellants' motion for an injunction on November 12, 1974. Since appellants now clearly abandon that position (Brief at 24), no more need be said about it except that the Court's opinion itself makes it abundantly clear that it found only that the agency had failed to give appellants proper notice of the grounds on which it ultimately proceeded. Accordingly, no res judicata effect can arise as to the single-entity theory.

Appellants now rely fully on their claim that there is, however, a res judicata effect arising from the May 2, 1974 decision in that the Court of Appeals "found" that the agency had "abandoned and conceded to be erroneous the theory that Alevaire must be tested by

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* Typical of such claims is the following:

> "Plaintiffs maintain that Alevaire is a single entity drug, the effectiveness of which was established in the prior proceedings by the Miller-Paez and Cohen studies...We here contend that defendants may not be allowed to relitigate the validity of the evidence proving Alevaire's effectiveness as a single-entity drug since that precise evidence was at issue and determined in plaintiffs' favor in the prior proceedings." (A 81)

comparing it to its vehicle." (Brief at 19) Moreover, appellants argue that

> "[W]e do contend that this Court found that defendants abandoned its position on those issues on the merits." (Brief at 24) (emphasis supplied).

Appellants recite at length words and phrases in the Court's opinion referring to abandonment or conceded errors, but fail to note any instance in which the Court found the agency to have thus acted on the merits of the issues before it, either as to the adequacy of the studies or the effectiveness of Alevaire. Rather, a reading of the Court's opinion makes clear that the Court was factually describing the agency's own actions, having made it explicit that it was not in any way ruling thereupon. Thus, the agency did abandon the single-entity theory but only in the sense that it was not contained in the August order whereas it had been in the March order. Further, the agency had conceded its March order to be erroneous in that it found some of its criticisms of the procedures used in the studies to have been wrong and on that basis decided to reconsider the hearing request by revoking the March order.*

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* The Court was referring to the agency's statement in its brief that it felt the order to be defective, and that the order was only before the court upon petitioners' insistence.

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In no instance did the Court purport to "find" the agency to have conceded the adequacy of the studies or the impropriety of the single-entity theory. In sum, the Court found no agency action on the merits, but rather explicitly declined to pass on the issues altogether, by dismissing the appeal.

It seems clear that the agency itself did not concede the propriety of the tests, as the quoted passage from its August order makes clear. Nor did its change of theories mean the appellants had persuaded the agency as to the invalidity of the single-entity theory. It is the absence of any decision on the merits by either the Court of Appeals or the agency which undercuts the res judicata/estoppel claims of appellants, for as each of the cases they cite makes clear, it is the fact of a decision on the merits which gives rise to the res judicata/estoppel effect. See Baltimore S.S. Co. v. Phillips, 274 U.S. 316, 319 (1927) ("If upon the same cause of action, the judgment or decree upon the merits in the first case is an absolute bar to the subsequent action..." (emphasis supplied); United States v. Utah Construction & Mining Co., 384 U.S. 394, 422 (1966) ("When an administrative agency... resolves disputed issues of fact before it. . . the courts have not hesitated to apply res

judicata to enforce repose." (emphasis supplied). Commissioner v. Sunnen, 333 U.S. 591, 598 (1948) ("But matters which were actually litigated and determined in the first proceeding cannot later be relitigated.") (emphasis supplied). IB Moore's Federal Practice, ¶0.405-7, 0.44-3. Absent any such determination in this case, appellants' claims must be rejected altogether.

Throughout these proceedings, the government, despite its several errors, has consistently attempted to compel appellants to undertake one simple series of tests, namely, to test the active ingredient or ingredients in Alevaire against the vehicle solution or the other ingredients. The reason for this is obvious. If Alevaire is no more effective than that solution despite the claims made on behalf of the active ingredients, and in particular, the miracle-ingredient tyloxapol, the public should not be induced to purchase and rely upon a less than effective product on whose behalf such false claims have been made.

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Plaintiffs have studiously avoided submitting such studies for some four years, and it must be assumed that either they have not conducted any such tests, or are unwilling to publicize the results of them.

Having overcome prior procedural defects, the agency has by the present notice given appellants a clear opportunity to demonstrate properly the effectiveness of their product as either a single-entity or a fixed-combination product (although the agency has determined Alevaire to be the latter) and has fully apprised them of the proper methods of so doing. (A 53) Appellees submit that appellants should now be required to come forward with such evidence, and their claims of effectiveness determined once and for all.

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POINT III

EVEN ASSUMING ARGUENDO THAT APPELLANTS CAN RAISE THE "NEW INFORMATION" ISSUE PRIOR TO EXHAUSTING THEIR ADMINISTRATIVE REMEDIES, THE AGENCY DOES POSSESS "NEW INFORMATION" AS REQUIRED BY 21 U.S.C. §355(e)

Section 355(e) requires the Secretary to withdraw approval of any drug application if he finds "on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved" that there is a lack of substantial evidence of effectiveness. Appellants claim here, as they did in the District Court, that the agency is barred from proceeding to withdraw approval of Alevaire because the agency has no "new information" that there is a lack of substantial evidence of effectiveness.

The government has previously shown that such claims are not judicially cognizable prior to their presentation to and determination by the agency itself both as a matter of law and of sound judicial and administrative policy. In fact, appellants' efforts to raise this issue at this stage of the proceedings is a case in point illustrating the wisdom of the exhaustion doctrine. Accordingly, Congress provided by statute that such issues must be raised before the agency in the first instance and that its decision is subject to judicial scrutiny by the Court of Appeals following final agency action. 21 U.S.C. §355(h). Even assuming

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arguendo that such claims are judicially cognizable prior to their presentation to and determination by the agency, it is clear that the agency possesses "new information" and is proceeding properly under the statute.

In the case of Alevaire, such new evidence is clearly provided by the 1968 NAS-NRC study itself, as well as subsequent re-evaluations thereof, and certain additional evidence, principally the labling of Alevaire, as the August 13th notice clearly indicates. Appellants initially argued in the District Court that the NAS-NRC study could not be used by the agency to satisfy the "new information" requirement because it had previously been employed in the prior agency proceedings, which, appellants claimed, had been terminated both by the Court of Appeals and by the agency itself, adversely to appellees.* Aside from the fallacious premise underlying this position, namely the view of the prior judicial and agency proceedings as having decided the merits of appellants' claim, it seems clear

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* As appellants argued below, in response to the claim that the new information requirement was satisfied by, inter alia, the NAS-NRC study, "[t]hat new information has been the subject of litigation which was resolved in favor of the plaintiffs and it can no longer, having been the subject of such litigation, support a new proceeding." (A 166) "Moreover, the NAS-NRC report on Alevaire has been merged into and is barred by the termination of the proceedings which began in 1968." (A 92). (A 147)

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both as a matter of statutory construction and as a matter of agency practice, that "new information" as used in §355(e), means any information made available after the application was initially approved. Nothing in the statute indicates that the agency is permitted to use a report or other evidence only once and must then disregard that information in future proceedings. The obvious intent of Congress as the statutory language indicates, was that all information be considered, whenever gathered, in assessing effectiveness. Indeed, even if appellants' view of the prior proceedings were correct, the agency would nevertheless not be barred from again using and relying upon the NAS-NRC study. Although this precise issue has apparently not been passed upon before, it has been held in Bell v. Goddard, 366 F.2d 177 (CA 7 1966), that approval of a drug can be withdrawn on the basis of a new application of existing information, such as a re-evaluation of previous clinical studies. Although arising in the context of an allegedly "unsafe" rather than an "ineffective" drug proceeding, the court there held that:

> We think that section 506(e) did not restrict the grounds for suspension to wholly new tests of a drug arising after the effective date of the application. The words "clinical experience" must be held to include such experience both prior and subsequent to the effectiveness of the petitioner's application... [T]his burden [of proving the drugs "unsafe"] could not be compounded by excluding relevant data existing when the application was approved. In this case an extensive re-evaluation, which drew together clinical experience in a matter not previously attempted and which perhaps brought its full impact to the attention of the experts for the first

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> time, provided the basis for the Commissioner's findings. An interpretation of the statute prohibiting such a new application of existing information would do violence to the paramount interest in protecting the public from unsafe drugs. The fact that the re-evaluation may have been inspired by a change in administrative policy is irrelevant. (emphasis supplied) 366 F.2d, at 177.

See also, Upjohn Co. v. Finch, 422 F.2d 944 (CA 6 1970).*

In the case of Alevaire, both the NAS-NRC study itself, the agency's re-evaluation thereof, the labeling and advertising of Alevaire, as described in the August 13th notice,** as well as other information all provide "new information" of precisely the type which Congress envisioned that the agency would use in proceeding against a drug product. The adequacy of that information to sustain the agency's determination and to meet the statutory requirements is a question which the Court of Appeals must decide after the agency has taken final action on a full record.

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*Appellants fail to note that in Upjohn the Court of Appeals examined the information which the Commissioner had "at the time he revoked the certifications" and not that which he had prior to the commencement of proceedings. 422 F.2d, at 944.

Appellants seem to suggest on the basis of Upjohn that the court should look to the substantiality of the "new information" which the agency has. The statute provides no such quantitative test, and more importantly, as Upjohn indicates, the weighing of the agency's evidence to determine whether it is sufficient to sustain the agency's action under the statute is a task explicitly assigned by Congress to the Court of Appeals following final agency action. 21 U.S.C. §355(h).

**The August 13th notice recites the agency's reliance on the labeling of Alevaire for its conclusion and recites one example thereof. The aforementioned brief submitted by the agency on appeal from the August 7th order sets out in much greater detail those labeling claims and contains copies of many advertisements of the product.

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Having finally acknowledged, albeit implicitly, that their initial argument, which was premised upon their fallacious res judicata/collateral estoppel theory, was wrong, appellants shift their position in this Court, claiming that while the report was sufficient to sustain proceedings against Alevaire as a single-entity product, it is not sufficient to show it to be a fixed combination product.

This argument simply obscures the true question here, for as the statute makes clear the "new information" requirement of section 355(e) is directed at the question of effectiveness, not at the question of whether a drug is a single-entity or a fixed-combination drug. Thus, the statutory language requires "new information. . . that there is a lack of substantial evidence of effectiveness." As the House Report on the bill makes clear:

> "[T]his section will . . . provide that approval of an application will be withdrawn . . . if new information, evaluated together with other evidence, indicates that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have. H. Rep. No. 2464, 87th Cong., 2d Sess. 8 (1962) (emphasis supplied).

See also S. Rep. No. 1744, 87th Cong., 2d Sess. Pt. I at 15, Pt. II at 6 (1962); H. Rep. No. 2536 [The Conference Report].

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The NAS-NRC study is directed precisely at the issue of effectiveness, and for that reason, it would, standing alone, meet the statutory requirement that the agency have new information that there is a lack of substantial evidence of effectiveness. Even assuming arguendo abandonment of the single-entity theory, that should hardly be deemed the equivalent of a concession that the NAS-NRC study is without value, since that study stands or falls on its own merits, independent of the particular gloss ("single-entity" or "fixed combination product") given to the study by the FDA at an earlier point in time. In other words, the critical issue is whether the experimental data relied upon in the NAS-NRC study can support an inference that Alevaire is ineffective, not whether those data can best be arranged under the "single entity" or "fixed combination product" labels.

In sum, it is new information as to effectiveness, not as to the agency's classificatory scheme which is required. Indeed, the classification of a drug as a single-entity product or a fixed-combination product is not even

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provided for by statute*, but was a practice undertaken by the agency in order to indicate to the drug manufacturers the type of studies and experiments which the agency felt were required to demonstrate the effectiveness of various drugs.* See 21 C.F.R. §§314.111(a)(5) and 3.86. The propriety of the agency's classification and hence its determination that a particular type of test is required is a matter clearly requiring an exercise of that agency's particular skill and expertise, subject to review by the Court of Appeals, following final agency action. 21 U.S.C. §355(h). The "new information" requirement, is, however, directed at a very different question, namely that of effectiveness.

The rationale underlying the "new information" requirement, which appellants so clearly recognize (Brief at 36) but then chose to ignore, is that in view of the substantial rights conferred by a grant of approval, or license to market a drug, the agency could not grant approval to a product, and then arbitrarily and without further or "new information", revoke that approval. As the procedural history in this case amply demonstrates (supra, at 11-14),

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* The fixed-combination classification was established on October 5, 1971, some three years after the Alevaire proceedings had commenced and nine years after the statute was enacted, 21 C.F.R. §3.86, although the NAS-NRC had used the designation internally as early as 1969.

Alevaire has never been threatened with the type of arbitrary grant and withdrawal of approval on grounds of effectiveness which the "new information" requirement was designed to guard against. Rather, the agency has proceeded solely on the basis of "new information" and has yet to grant approval to Alevaire as an effective drug.

The wisdom of the exhaustion doctrine which requires having the agency determine such claims in the first instance is particularly well-illustrated here, for appellants in reality call upon this Court to anticipate the use the agency will ultimately make of this report and other information before it. In so doing, they ask this Court to ignore the particular expertise and knowledge of the agency and to make a judgment which necessarily cannot be made except upon a full record following final agency action. As the Supreme Court observed in Aircraft & Diesel Corp. v. Hirsch, 331 U.S. 752, 767-68 (1947):

> The very purpose of providing either an exclusive or initial and preliminary administrative determination is to secure the administrative judgment either, in the one case, in substitution for judicial decision or, in the other, as foundation for or perchance to make unnecessary later judicial proceedings. Where Congress had clearly commanded that administrative judgment be taken initially or exclusively, the courts have no lawful function to anticipate the administrative decision with their own . . . To do this not only would contravene the will of Congress as a matter of restricting or deferring judicial action. It would nullify the congressional objects in providing the administrative determination."

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If this request to anticipate agency action were granted in this case, all agency orders would be subject to requests for preliminary judicial scrutiny to determine the sufficiency of the basis for those proceedings. This is contrary to the clear intent of Congress that such review follow only upon final agency action.

While the Court of Appeals did note in its May 2, 1974 decision that "there is little in the record now before us to support the proposition that Alevaire is a fixed combination drug within the meaning of 21 C.F.R. §3.86. . .", it went on to state that "it is not for this Court to pass on the question on this appeal." (A 52) Rather, as the Court noted after following the procedures outlined in section 355(e),

> "The FDA may then determine the question on a full and proper record, subject, of course, to petitioners' right of appeal to this Court from an adverse determination." 503 F.2d, at 633 (A52).

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Attempting to anticipate the use the agency will make of information already in its possession or to guess what additional information may be produced during its proceedings, demonstrates the absurd consequences of permitting courts to scrutinize claims such as these without the benefit of the agency's judgment and prior to final agency action, and makes clear the threat which such a practice would pose to the operation of both the courts and the agencies in the future.

CONCLUSION

For the reasons set forth above, the order of the District Court should be affirmed, and the agency thereby permitted to go forward with its proceedings.

Respectfully submitted,

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December 10, 1974

74-3522

Form 280 A-Affidavit of Service by Mail
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AFFIDAVIT OF MAILING

State of New York)
County of New York) ss

Pauline Troia, being duly sworn, deposes and says that she is employed in the Office of the United States Attorney for the Southern District of New York.

That on the 10th day of December 1974 she served a copy of the within

govt's brief

by placing the same in a properly postpaid franked envelope addressed:

Rogers, Hoge & Hills, Esqs.,
90 Park Ave.
New York, NY 10016

And deponent further says she sealed the said envelope and placed the same in the mail chute drop for mailing in the United States Courthouse, Foley Square, Borough of Manhattan, City of New York.

Pauline Troia

Sworn to before me this

10th day of December 19 74

Walter G. Brannon

WALTER G. BRANNON
Notary Public, State of New York
No. 24-0304500
Qualified in Kings County
Cert. filed in New York County
Term Expires March 30, 1975